

# 2018 Current Fiscal Year Report: Task Force on Research Specific to Pregnant Women and Lactating Women

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## 1. Department or Agency

Department of Health and Human Services

## 2. Fiscal Year

2018

## 3. Committee or Subcommittee

Task Force on Research Specific to Pregnant Women and Lactating Women

## 3b. GSA

## Committee No.

2603

## 4. Is this New During Fiscal Year?

No

## 5. Current Charter

03/13/2017

## 6. Expected Renewal Date

03/13/2019

## 7. Expected Term Date

## 8a. Was Terminated During Fiscal Year?

No

## 8b. Specific Termination Authority

Not Applicable

## 8c. Actual Term Date

## 9. Agency Recommendation for Next Fiscal Year

Continue

## 10a. Legislation Req to Terminate?

Not Applicable

## 10b. Legislation Pending?

Not Applicable

## 11. Establishment Authority Statutory (Congress Created)

## 12. Specific Establishment Authority

Section 2041 of the 21st Century Cures Act, P.L. 114-255

## 13. Effective Date

12/13/2016

## 14. Committee Type

Continuing

## 14c. Presidential?

No

## 15. Description of Committee Scientific Technical Program Advisory Board

## 16a. Total Number of Reports

1

## 16b. Report

Date

Report Title

09/13/2018

TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN

## Number of Committee Reports Listed: 1

17a. Open 3 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 3

## Meetings and Dates

### Purpose

Program Advisory

Program Advisory

Program Advisory

### Start

11/06/2017

02/26/2018

05/14/2018

### End

- 11/07/2017

- 02/27/2018

- 05/15/2018

## Number of Committee Meetings Listed: 3

## Current FY

## Next FY

## 18a(1). Personnel Pmts to Non-Federal Members

\$0.00

\$0.00

## 18a(2). Personnel Pmts to Federal Members

\$0.00

\$0.00

<b>18a(3). Personnel Pmts to Federal Staff</b>	\$159,397.00	\$139,451.00
<b>18a(4). Personnel Pmts to Non-Member Consultants</b>	\$0.00	\$0.00
<b>18b(1). Travel and Per Diem to Non-Federal Members</b>	\$16,583.00	\$10,945.00
<b>18b(2). Travel and Per Diem to Federal Members</b>	\$0.00	\$0.00
<b>18b(3). Travel and Per Diem to Federal Staff</b>	\$0.00	\$0.00
<b>18b(4). Travel and Per Diem to Non-member Consultants</b>	\$0.00	\$0.00
<b>18c. Other(rents,user charges, graphics, printing, mail, etc.)</b>	\$38,784.00	\$19,604.00
<b>18d. Total</b>	\$214,764.00	\$170,000.00
<b>19. Federal Staff Support Years (FTE)</b>	0.80	0.70

**20a. How does the Committee accomplish its purpose?**

The Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) was established under section 2041 of the 21st Century Cures Act, P.L.114-255 to provide advice and guidance to the Secretary of Department of Health and Human Services regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities. The committee prepared and submitted to the HHS Secretary and Congress a report to correspond with the legislative requirements under the 21st Century Cures Act.

**20b. How does the Committee balance its membership?**

The Task Force is composed of both Federal and non-Federal members. Currently in this reporting period, the committee includes 16 federal members and 10 non-federal members.

**20c. How frequent and relevant are the Committee Meetings?**

Meetings of the full Task Force are held not less than two times each year or more frequently, as appropriate, to fulfill its duties. During this reporting period, the committee met once in 2017 (November 2017) and twice in 2018 (February and May 2018).

**20d. Why can't the advice or information this committee provides be obtained elsewhere?**

The 21st Century Cures Act established PRGLAC to advise the Secretary of Health and Human Services regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women. The committee is tasked with identifying these gaps and will report its findings back to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives. The quality, scope, and balance of advice

from this committee cannot be obtained from NIH staff or from other established source because the membership of the committee is constituted to meet the specific requirements mandated in legislation.

## **20e. Why is it necessary to close and/or partially closed committee meetings?**

Not Applicable

## **21. Remarks**

Reports: The Task Force sent its final report, including 15 recommendations, to HHS by the deadline of September 13, 2018. The DFO and Decision Maker are the same person based on the assignment of duties within the Center. Although the committee has submitted a final report, projected costs have been included if the committee is required to meet again in FY19. Members: Dr. Spong resigned as the Chair effective 6/30/2018. Dr. Bianchi has taken her place as the Chair effective 7/1/2018.

## **Designated Federal Officer**

Lisa Kaeser Director, Office of Legislation and Public Policy

<b>Committee Members</b>	<b>Start</b>	<b>End</b>	<b>Occupation</b>	<b>Member Designation</b>
ADIRIM, TERRY	05/01/2017	03/13/2021	DEPUTY ASSISTANT SECRETARY OF DEFENSE, DOD	Regular Government Employee (RGE) Member
AVENEVOLI, SHELLI	05/01/2017	03/13/2021	DEPUTY DIRECTOR, NIMH	Regular Government Employee (RGE) Member
BIANCHI, DIANA	07/01/2017	03/13/2021	DIRECTOR, NICHD	Regular Government Employee (RGE) Member
BOK, KARIN	05/01/2017	03/13/2021	SENIOR VACCINE SCIENCE ADVISOR	Regular Government Employee (RGE) Member
BREMER, ANDREW	05/01/2017	03/13/2021	CHIEF, PGNB, NICHD	Regular Government Employee (RGE) Member
BUCCI-RECHTWEG, CHRISTINA	02/18/2018	03/13/2021	HEAD	Special Government Employee (SGE) Member
FABIYI, CAMILLE	05/01/2017	03/13/2021	SENIOR ADVISOR FOR WOMEN'S HEALTH, AHRQ	Regular Government Employee (RGE) Member
FOLEY, STEVEN	02/18/2018	03/13/2021	OB/GYN PHYSICIAN	Special Government Employee (SGE) Member
GIVENS, SUSAN	02/18/2018	03/13/2021	LAMAZE CERTIFIED CHILDBIRTH EDUCATOR	Special Government Employee (SGE) Member
GORMAN, MELISSA	02/18/2018	03/13/2021	EDUCATION COORDINATOR	Special Government Employee (SGE) Member
GORODETSKY, ELENA	05/01/2017	03/13/2021	RESEARCH PROGRAM OFFICER, ORWH	Regular Government Employee (RGE) Member
JENKINS, MARJORIE	05/01/2017	03/13/2021	DIRECTOR, MEDICAL INITIATIVES, FDA	Regular Government Employee (RGE) Member
JONES, BRIDGETTE	02/18/2018	03/13/2021	ASSOCIATE PROFESSOR OF PEDIATRICS	Special Government Employee (SGE) Member
KOURTIS, ATHENA	05/01/2017	03/13/2021	LEAD MEDICAL OFFICER, CDC	Regular Government Employee (RGE) Member
LENGYEL, KRISTI	02/18/2018	03/13/2021	DIRECTOR OF PATIENT ADVOCACY	Special Government Employee (SGE) Member
LIPSON, LINDA	05/01/2017	03/13/2021	SCIENTIFIC PROGRAM MANAGER, VA	Regular Government Employee (RGE) Member

NAGEL, JOAN	05/01/2017 03/13/2021	PROGRAM DIRECTOR, NCATS	Regular Government Employee (RGE) Member
PEMBERTON, VICTORIA	05/01/2017 03/13/2021	CLINICAL TRIALS SPECIALIST, NHLBI	Regular Government Employee (RGE) Member
PIPER, JEANNA	05/01/2017 03/13/2021	SENIOR MEDICAL OFFICER, NIAID	Regular Government Employee (RGE) Member
SHEFFIELD, JEANNE	02/18/2018 03/13/2021	DIRECTOR	Special Government Employee (SGE) Member
SPATZ, DIANE	02/18/2018 03/13/2021	THE HELEN M. SHEARER PROFESSOR OF NUTRITION	Special Government Employee (SGE) Member
SPONG, CATHERINE	05/01/2017 06/30/2018	DEPUTY DIRECTOR, NICHD	Regular Government Employee (RGE) Member
TERNIK, ROBERT	02/18/2018 03/13/2021	SENIOR RESEARCH ADVISOR	Special Government Employee (SGE) Member
TSCHETTER, LOIS	02/18/2018 03/13/2021	ASSISTANT DEAN, UNDERGRADUATE NURSING	Special Government Employee (SGE) Member
UDDIN, SAYEEDHA	05/01/2017 03/13/2021	SENIOR PUBLIC HEALTH ANALYST	Regular Government Employee (RGE) Member
WILSON, LEE	05/01/2017 03/13/2021	SENIOR ADVISOR, HRSA	Regular Government Employee (RGE) Member

### Number of Committee Members Listed: 26

### Narrative Description

NICHD conducts and supports research in the United States and throughout the world on fetal, infant and child development; maternal, child and family health; reproductive biology and population issues; and medical rehabilitation. Currently, insufficient information exists to guide the care and treatment of pregnant women in many areas. For instance, the safety, efficacy, and dosing of medications approved for the general population may not apply to pregnant or nursing women. PRGLAC will review current research on pregnancy and lactation, identify ethical issues surrounding the inclusion of pregnant women and nursing mothers in clinical research, and chronicle the federal activities that focus on therapies for pregnant women and nursing mothers. The effort will include a focus on specific drugs, formulations, and other pharmacological factors that may affect health outcomes for pregnant women and nursing mothers and their children.

### What are the most significant program outcomes associated with this committee?

Checked if Applies

Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input checked="" type="checkbox"/>
Increased customer satisfaction	<input type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>

Other

☐

### Outcome Comments

Outcome Major Policy Changes: It depends on the Secretary's response. Outcome Improved Service Delivery: Improved information relevant to therapeutics used by pregnant women and lactating women; depends on implementation of report.

### What are the cost savings associated with this committee?

Checked if Applies

None

☐

Unable to Determine

☒

Under \$100,000

☐

\$100,000 - \$500,000

☐

\$500,001 - \$1,000,000

☐

\$1,000,001 - \$5,000,000

☐

\$5,000,001 - \$10,000,000

☐

Over \$10,000,000

☐

Cost Savings Other

☐

### Cost Savings Comments

Not Applicable

### What is the approximate Number of recommendations produced by this committee for the life of the committee?

15

### Number of Recommendations Comments

The Task Force sent its final report, including 15 recommendations, to HHS by the deadline of September 13, 2018.

### What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

0%

### % of Recommendations Fully Implemented Comments

The HHS Secretary has until December 2018 to decide whether to implement any of the Task Force's recommendations.

### What is the approximate Percentage of these recommendations that have been or

**will be Partially implemented by the agency?**

0%

**% of Recommendations Partially Implemented Comments**

The HHS Secretary has until December 2018 to decide whether to implement any of the Task Force's recommendations.

**Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?**

Yes ☒ No ☐ Not Applicable ☐

**Agency Feedback Comments**

NICHD led the Task Force for the NIH. Multiple federal agencies and other input incorporated into the final recommendations/report.

**What other actions has the agency taken as a result of the committee's advice or recommendation?**

Checked if Applies

Reorganized Priorities	<input type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input type="checkbox"/>

**Action Comments**

All of the above actions are possible; depends on the responses from the Secretary, from Congress, and internally (NICHD is undertaking a strategic planning process).

**Is the Committee engaged in the review of applications for grants?**

No

**Grant Review Comments**

Not Applicable

**How is access provided to the information for the Committee's documentation?**

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>

Online Committee Web Site  
Online GSA FACA Web Site  
Publications  
Other

<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

**Access Comments**

Not Applicable